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90/007,903	01/25/2006	6565509	518852800400	5800

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MERCHANT & GOULD PC
 P.O. BOX 2903
 MINNEAPOLIS, MN 55402-0903

EXAMINER

Erik Kielin

ART UNIT	PAPER NUMBER
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3992

IFW

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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PENG CHEN and RICHARD KIM
MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE, SUITE 100
SAN DIEGO, CA 92130-2040

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/007,903.

PATENT NO. 6565509.

ART UNIT 3992.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination	
	90/007,903	6565509	
	Examiner	Art Unit	
	Erik Kielin	3992	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 25 January 2006 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☒ PTO-892, b) ☐ PTO-1449, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the date of service of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) ☐ by Treasury check or,
b) ☐ by credit to Deposit Account No. _____, or
c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

Erik Kielin
Primary Examiner
Art Unit: 3992

cc:Requester (if third party requester)

Application/Control Number: 90/007,903

Page 2

Art Unit: 3992

DECISION ON REQUEST FOR REEXAMINATION

A substantial new question of patentability affecting claims 1-19, 24-26, and 35-38 of Patent Number US 6,565,509 to James Say et al. (the '509 patent, hereafter) is raised by the request for *ex parte* reexamination.

Requester-Provided References

- (1) EP Patent Application No. 83106571.9 to Shichiri et al., entitled "Portable Artificial Pancreas," filed July 5, 1983, published January 18, 1984 as EP publication no. 0098592 A2 (hereinafter "Shichiri I")
- (2) Shichiri et al., "Telemetry Glucose Monitoring Device With Needle-Type Glucose Sensor: A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals," *Diabetes Care*, Vol. 9, No. 3, pp. 298-301, May-June 1986 (hereinafter "Shichiri II")
- (3) Ko et al., (Ed.), "Implantable Sensors for Closed-Loop Prosthetic Systems," Mount Kisco, NY: Futura Publishing Company, Inc., 1985, Chapter 15, entitled "Needle-type Glucose Sensor for Wearable Artificial Endocrine Pancreas," pp. 197-210 (hereinafter, "Shichiri III")
- (4) U.S. Patent No. 5,569,186 to Lord et al., entitled "Closed Loop Infusion Pump System With Removable Glucose Sensor," filed April 25, 1994, issued October 29, 1996 (hereinafter "Lord I")
- (5) U.S. Patent No. 4,494,950 to Fischell, entitled "Plural Module Medication Delivery System," filed January 19, 1982 and issued January 22, 1985 (hereinafter "Fischell")
- (6) M. Shichiri et al., "Glycaemic Control in Pancreatectomized Dogs with a Wearable Artificial Endocrine Pancreas," *Diabetologia* (1983) 24:179-184, Springer-Verlag 1983 (hereinafter "Shichiri IV")
- (7) U.S. Patent No. 5,390,671 to Lord et al., entitled "Transcutaneous Sensor Insertion Set," filed March 15, 1994, issued February 21, 1995 (hereinafter "Lord II")
- (8) PCT Application No. PCT/US96/02006 to Cheney et al., entitled "Transcutaneous Sensor Insertion Set," filed February 14, 1996, claiming priority to U.S. application no. 08/393,159, published on August 22, 1996 as WO 96/25089 (hereinafter "Cheney")
- (9) U.S. Patent No. 5,957,854 to Besson et al., entitled "Wireless Medical Diagnosis And Monitoring Equipment," filed December 5, 1997, claiming priority to PCT/EP94/02926, filed September 2, 1994 (now U.S. 5,862,803) (hereinafter "Besson")
- (10) U.S. Patent No. 6,219,574 to Cormier et al., entitled "Device And Method For Enhancing Transdermal Sampling," filed June 17, 1997, claiming priority to provisional application no. 60/019,990, filed June 18, 1996, issued on April 17, 2001 (hereinafter "Cormier")

Application/Control Number: 90/007,903

Page 3

Art Unit: 3992

(11) U.S. Patent No. 4,703,756 to Gough et al., entitled "Complete Glucose Monitoring System With An Implantable Telemetered Sensor Module," filed May 6, 1986, issued November 3, 1987 (hereinafter "Gough")

(12) Stuart J. Updike et al., "Principles of Long-term Fully Implanted Sensors With Emphasis On Radiotelemetric Monitoring of Blood Glucose From Inside a Subcutaneous Foreign Body Capsule (FBC)," *Biosensors in the Body: Continuous in vivo Monitoring*, Edited by David M. Fraser, Chapter 4, pp. 117-137, April 16, 1997, John Wiley & Sons Ltd, (hereinafter "Updike")

(13) Mark C. Shults et al., "A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Implanted Glucose Sensors," *IEEE Transactions On Biomedical Engineering*, Vol. 41, No. 10, pp. 937-942, October 1994, 1994 IEEE (hereinafter "Shults")

(14) Brian D. McKean et al. "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," *IEEE Transactions On Biomedical Engineering*, Vol. 35, No. 7, July 1988 IEEE (hereinafter "McKean")

(15) Jon C. Armour et al., "Application of Chronic Intravascular Blood Glucose Sensor in Dogs," *Diabetes*, Vol. 39, December 1990 (hereinafter "Armour")

(16) Michael Thompson et al., "In Vivo Probes: Problems and Perspectives," *Clinical Biochemistry*, Vol. 19, October 1986 (hereinafter "Thompson")

(17) G. Velho et al., "Strategies for calibrating a subcutaneous glucose sensor," *Biomed. Biochim. Acta* 48 (presented at the International Workshop on Intracorporeal Glucose Sensors," September 27-30, 1988, Gohren-Lebbin, GDR) (hereinafter "Velho")

Prosecution History

The application (09/667,199; the '199 application hereafter) that became the '509 patent applied only the reference US 5,711,861 to Ward et al. (the '199 application; paper filed 24 July 2002). As argued by Applicant at that time, Ward teaches only a subcutaneous sensor as opposed to a transcutaneous sensor (see Applicant's Response filed 14 November 2002). No other comments were provided by the examiner of the '199 application regarding the reasons for allowing the claims.

Accordingly, a reference teaching a transcutaneous sensor would raise a substantial new question of patentability as to at least one claim of the '509 patent.

Application/Control Number: 90/007,903

Page 4

Art Unit: 3992

Substantial New Question of Patentability

(1) The Request indicates that Requester believes claims 1, 2, 5-7, 9-11, 14-17, 19, 24-26, and 36-38 are anticipated by each of Shichiri I, Shichiri II, and Shichiri III. (See Request at pages 10-17, 23-26, 41-52, and 54-61.)

Before beginning, Examiner notes that Requester states "Shichiri II and Shichiri III have the same or very similar disclosures as Shichiri I (Request, p. 12, third paragraph). For the purposes of determining a substantial new question of patentability, then, Shichiri II and Shichiri III are taken to be cumulative references to Shichiri I. (See also Request at pages 16-17.)

Examiner incorporates by reference, the locations in Shichiri I, as cited in the Request, wherein the features of the above claims can be found. Of particular relevance, Shichiri I discloses the **transcutaneous** sensor **13** connected to a sensor control unit **2** (Figs. 1-3) including an RF transmitter (Fig. 1), as opposed to the **subcutaneous** sensor of Ward as applied by the examiner of the '199 application. Shichiri I (and Shichiri II and III) provides a new teaching (the transcutaneous sensor) not before the examiner of the '199 application. There is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Shichiri I raises a substantial new question of patentability as to at least claims 1, 2, 5-7, 9-11, 14-17, 19, 24-26, and 36-38.

(2) The Request indicates that Requester believes claims 1, 2, 5, 6, 10-12, 14, 17, 19, 24-26, and 36-38 are anticipated by Lord I. (See Request at pages 10-11, 17-20, 41-43, 46-50, 52-53, and 54-61.)

The above substantial new question of patentability is based solely on patents and/or printed publications already cited/considered in an earlier concluded examination of the patent being reexamined. On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a **case-by-case basis**.

In the present instance, there exists a SNQ based solely on Lord I. A discussion of the specifics now follows:

Application/Control Number: 90/007,903

Page 5

Art Unit: 3992

While Lord I was present before the examiner during the examination of the '199 application, the reference was not relied on to reject the claims. When a substantial new question of patentability is raised solely over previously cited art, the Court stated in the sole footnote, in *In re Robert T. Bass*, 314 F.3d 575, 576-77, 65 USPQ2d 1156, 1157 (Fed. Cir. 2002), in pertinent part,

"37 CFR 1.2 requires that all Office business be transacted in writing. Thus, the Office cannot presume that a prior art reference was previously relied upon or discussed in a prior Office proceeding if there is no basis in the written record to so conclude other than the examiner's initials or a check mark on a PTO 1449 form, or equivalent, submitted with an information disclosure statement. Thus, any specific discussion of prior art must appear on the record of a prior related Office proceeding."

Because no written consideration of Lord I exists in the record of the '199 application, Lord I cannot be excluded as a reference raising a substantial new question of patentability.

Examiner incorporates by reference, the locations in Lord I, as cited in the Request, wherein the features of the above claims can be found. Of particular relevance, Lord I discloses the **transcutaneous** glucose sensor **20** (Figs. 1-3) connected to a sensor control unit including an RF transmitter **26** (Fig. 1), as opposed to the **subcutaneous** sensor of Ward as applied by the examiner of the '199 application. There is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not the claims are patentable. Accordingly, Lord I raises a substantial new question of patentability as to at least claims 1, 2, 5, 6, 10-12, 14, 17, 19, 24-26, and 36-38.

(3) The Request indicates that Requester believes claims 1, 4, 6, 8-11, and 13 are obvious over Fischell in view of Shichiri IV. (See Request at pages 10-11, 21-23, 36, and 44-49.)

Examiner incorporates by reference, the locations in Fischell, as cited in the Request, wherein the features of the above claims can be found. Of particular relevance, Fischell discloses the **transcutaneous** sensor **14b** (Figs. 1 and 4) connected to a sensor control unit **14a** (Fig. 4) including an RF transmitter **65** (Fig. 4), as opposed to the **subcutaneous** sensor of Ward as applied by the examiner of the '199 application.

Also, as pointed out in the Request at p. 21, Fischell suggests that the transcutaneous sensor **14b** may be "a glucose sensor on the tip of a needle" (Fischell, col. 6, lines 11-12). Fischell also indicates that a **known**, transcutaneous glucose sensor, located on the tip of a needle is disclosed in Shichiri IV (Fischell, col. 2, lines 30-40). Shichiri IV provides the details of the sensor left undiscussed in Fischell.

There is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, Fischell

Application/Control Number: 90/007,903

Page 6

Art Unit: 3992

considered with Shichiri IV raises a substantial new question of patentability as to at least claims 1, 4, 6, 8-11, and 13.

(4) The Request indicates that Requester believes claims 2-4 are obvious over any of Lord I, Shichiri I, Shichiri II, and Shichiri III in view of either of Lord II and Cheney. (See Request at pages 10-11 and 23-41.)

Again, of Shichiri I, II, and III, Shichiri I is representative.

Note, Lord II was of record during the examination of the '199 application; therefore, the combination of Lord I with Lord II is based solely on "old art." As above, the examiner of the '199 patent made no mention of the Lord II patent either, much less the combination. For the reasons indicated above, the combination of Lord I and Lord II cannot be excluded from raising a substantial new question of patentability.

Lord II and Cheney share common inventors: Peter Lord and Paul Cheney. Accordingly, the disclosures are similar. Also, Lord I and Lord II share Peter Lord as a common inventor.

Examiner incorporates by reference, the locations in Lord II and Cheney, as cited in the Request, wherein the features of the above claims can be found.

With respect to claims 2, 3, and 4, Lord II (like Lord I and Shichiri I) discloses a thin-film, electrochemical sensor **12** including on a planar, flexible substrate **22**, **24** having working electrodes **18** inserted beneath the skin in direct contact with the host's blood that are connected via conductive traces **20** to conductive contact pads **30** that protrude outwardly from beneath the skin (Lord II, Figs. 1-3; col. 3, lines 32-64) ('509 claim 2). The contact pads **30** extending out of the skin, are used to make an electrical connection to the sensor control unit **32** (called "monitor" in Lord II) ('509 claim 2). As shown in Fig. 1, the sensor control unit **32** is adapted to receive the portion of the sensor **12** protruding from the beneath skin ('509 claim 3) and is adapted for placement on the skin over an insertion site of the transcutaneous electrochemical sensor **12** ('509 claim 4). Considered with the features disclosed in either Lord I or Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, either of Lord I and Shichiri I considered with Lord II raises a substantial new question of patentability as to claims 2-4 of the '509 patent.

Similar to Lord II, Cheney discloses a thin-film, electrochemical sensor **12** including on a planar, flexible substrate (polyimide) having working electrodes **18** inserted beneath the skin in direct contact with the host's blood that are connected via conductive traces **20** to conductive contact pads **22** that protrude outwardly from beneath the skin (Cheney Figs. 1 and 2; pages 6-8) ('509 claim 2). The contact pads **22** extending out of the skin, are used to make an electrical connection to the sensor control unit **24** (called "monitor" in Lord II) ('509 claim 2). As shown in Figs. 1 and 2, the sensor control unit **24** is adapted to receive the portion of the sensor **12**

Application/Control Number: 90/007,903

Page 7

Art Unit: 3992

protruding from the beneath skin ('509 claim 3) and is adapted for placement on the skin over an insertion site of the transcutaneous electrochemical sensor 12 ('509 claim 4). Considered with the features disclosed in either Lord I or Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, either of Lord I and Shichiri I considered with Cheney raises a substantial new question of patentability as to claims 2-4 of the '509 patent.

(5) The Request indicates that Requester believes claim 4 is obvious over any of Lord I, Shichiri I, Shichiri II, and Shichiri III in view of either of Besson and Cormier. (See Request at pages 10-11 and 36-41.)

Again, of Shichiri I, II, and III, Shichiri I is representative.

Examiner incorporates by reference, the locations in each of Besson and Cormier, as cited in the Request, wherein the features of the above claims can be found.

Each of Besson and Cormier teach a sensor control unit placement over the insertion point of the sensor. (See Besson, Fig. 2c and see Cormier Figs. 1-10). Considered with the features disclosed in either Lord I or Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, either of Lord I and Shichiri I considered with either of Besson and Cormier raises a substantial new question of patentability as to claim 4 of the '509 patent.

(6) The Request indicates that Requester believes claim 5 is obvious over any of Lord I, Shichiri I, Shichiri II, and Shichiri III in view of Cormier. (See Request at pages 10-11, 41-43.)

Again, of Shichiri I, II, and III, Shichiri I is representative.

Examiner incorporates by reference, the locations in Cormier, as cited in the Request, wherein the features of the above claims can be found.

Cormier teaches the sensor control unit is water resistant or water proof (Cormier, col. 9, lines 37-41). Considered with the features disclosed in either Lord I or Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, either of Lord I and Shichiri I considered with Cormier raises a substantial new question of patentability as to claim 5 of the '509 patent.

(7) The Request indicates that Requester believes claim 8 is obvious over any of Lord I, Shichiri I, Shichiri II, and Shichiri III in view of Besson. (See Request at pages 10-11 and 44-45.)

Application/Control Number: 90/007,903

Page 8

Art Unit: 3992

Examiner incorporates by reference, the locations in Besson, as cited in the Request, wherein the features of the above claims can be found.

Besson teaches that the electrodes 2 each contain a transmitting unit 31 and a receiving unit 30. Considered with the features disclosed in either Lord I or Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, either of Lord I and Shichiri I considered with Besson raises a substantial new question of patentability as to claim 8 of the '509 patent.

(8) The Request indicates that Requester believes claim 13 is obvious over any of Shichiri I, Shichiri II, and Shichiri III in view of Besson. (See Request at pages 10-11 and 49.)

Again, of Shichiri I, II, and III, Shichiri I is representative.

Examiner incorporates by reference, the locations in Besson, as cited in the Request, wherein the features of the above claims can be found.

Besson teaches that the electrodes 2 each contain a transmitting unit 31 and a receiving unit 30. Considered with the features disclosed in Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, Shichiri I considered with Besson raises a substantial new question of patentability as to claim 13 of the '509 patent.

(9) The Request indicates that Requester believes claims 2, 15, 16, and 18 are obvious over Shichiri I alone. (See Request at pages 10-11, 33-34, 50-51 and 53.)

Examiner incorporates by reference, the locations in Shichiri I, as cited in the Request, wherein the features of the above claims can be found.

For the reasons indicated above under section labeled "(1)" Shichiri I raises a substantial new question of patentability as to claims 2, 15, 16, and 18.

(10) The Request indicates that Requester believes claims 15 and 16 are obvious over Shichiri I in view of either of Shichiri II and Besson. (See Request at pages 10-11 and 50-52.)

Examiner incorporates by reference, the locations in Shichiri II and Besson, as cited in the Request, wherein the features of the above claims can be found.

Application/Control Number: 90/007,903

Page 9

Art Unit: 3992

Shichiri II and Besson each teach calibration of the sensors, which is suggestive of a calibration unit. Considered with the features disclosed in Shichiri I, there is a substantial likelihood that a reasonable examiner would consider this combined teaching important in deciding whether or not the claims are patentable. Accordingly, Shichiri I considered with either of Shichiri II and Besson raises a substantial new question of patentability as to claims 15 and 16 of the '509 patent.

(11) The Request indicates that Requester believes claim 35 is obvious over either of Shichiri I and Lord I in view of Besson. (See Request at pages 10-11 and 59.)

Examiner incorporates by reference, the locations in Besson, as cited in the Request, wherein the features of the above claims can be found.

Besson teaches a temperature measuring device. However, there is no suggestion in any of the references, particularly Besson, that the temperature measurement device is used to correct data obtained from the sensor, as alleged by Requestor. Requestor errs in this statement. Furthermore there is a substantial likelihood that a reasonable examiner would **NOT** consider this combined teaching important in deciding whether or not claim 35 is patentable because the feature itself is not taught. Accordingly, the Request **fails** to raise a substantial new question of patentability as to claim 35.

Conclusion

So long as a substantial new question of patentability has been raised with respect to at least one claim, all claims are subject to reexamination. Accordingly, **all claims 1-56 are subject to reexamination.**

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in reexamination proceedings are provided for in 37 CFR 1.550(c).

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner of the third party requester must be served on the other party (or parties where two or more third-party-requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. US 6,565,509 throughout the course of this reexamination proceeding. The third party requester

Application/Control Number: 90/007,903

Page 10

Art Unit: 3992

is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
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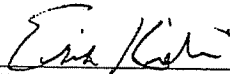
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Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.


Signed:



Erik Kielin
Primary Examiner
Central Reexam Unit 3992
(571) 272-1693

March 22, 2006

Conferees:

 SPRE-CRG - 3992
